IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CINDY LEE BROCK, et al.,

Plaintiffs,

v. Civil Action No. 2:12-cv-5114

C. R. BARD, INC.,

Defendant.

AMENDED MEMORANDUM OPINION AND ORDER

The Memorandum Opinion and Order entered March 21, 2017 [ECF No. 187] is hereby amended for erroneous ECF numbers.

Pending before the court are all remaining pretrial motions. All are ripe for adjudication.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 7,000 of which are in the Bard MDL, MDL 2187. In an effort to efficiently and effectively manage this MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled

on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order ("PTO") # 102, No. 2:10-md-2187 [ECF No. 729]. This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Thereafter, I entered orders on subsequent waves. Ms. Brock's case was selected as a Wave 2 case by the plaintiffs. PTO # 118, No. 2:10-md-2187 [ECF No. 841].

II. Legal Standards

a. Summary Judgment

To obtain summary judgment, "the movant must show that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In turn, to avoid summary judgment, the nonmovant must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

b. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir.

1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, as the plaintiff did here, I consult the choice-of-law rules of the state in which the implantation surgery took place—in this case, Georgia. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.").

The parties agree, as does this court, that these principles compel application of Georgia law. Under Georgia law, tort cases are "governed by the rule of *lex loci delicti*, which requires application of the substantive law of the place where the tort or wrong occurred." *Carroll Fullmer Logistics Corp. v. Hines*, 710 S.E.2d 888, 890 (Ga. Ct. App. 2011) (citing *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413, 419 (Ga. 2005)). Here, the alleged wrong occurred in Georgia, where Ms. Brock was implanted with the allegedly defective devices. Thus, I apply Georgia's substantive law to the claims in this case.

c. Daubert Motions – Specific Causation

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). An expert may be qualified to offer expert

testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702.

In the context of specific causation expert opinions, the Fourth Circuit has held that "a reliable differential diagnosis provides a valid foundation for an expert opinion." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262–63 (4th Cir. 1999). "A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation." *Id.* at 265. However, an expert's causation opinions will not be excluded "because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." *Id.* At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001).

III. Discussion

a. Bard's Motion for Summary Judgment [ECF No. 45]

Bard's Motion for Summary Judgment [ECF No. 45] is **GRANTED in part** as to the following conceded claims: manufacturing defect, breach of warranty, and failure to warn.

For the following reasons, Bard's Motion for Summary Judgment [ECF No. 45] is also **GRANTED in part** as to the following claims: negligent inspection, marketing, labeling, packaging, and selling. "In Georgia, the essential elements of a cause of action for negligence are: (1) a legal duty; (2) a breach of this duty; (3) an injury; and (4) a causal connection between the breach and the injury." *Vaughan v. Glymph*, 526

S.E.2d 357, 359 (Ga. App. Ct. 1999).

Bard contends that the plaintiffs' claims for negligent inspection, packaging, marketing, and selling of the product fail for lack of evidence. The plaintiffs argue that Bard misconstrues the nature of their negligence argument, and that their allegations regarding the inspection, marketing, labeling, packaging, and selling of the product comprise part of their general negligence claim, rather than distinct theories of recovery. In short, the plaintiffs assert that Bard failed to adequately study or test its mesh products to determine if the products were adequately safe.

A review of the plaintiffs' Count I in the Master Complaint, Master Compl. ¶¶ 62–67, No. 2:10-md-2187 [ECF No. 199], reveals that the plaintiffs asserted three distinct negligence theories under "Count I." The bulk of the Count I allegations make claims for negligent failure to warn and negligent design defect. The other negligence allegations posit that Bard was "negligent . . . in designing, manufacturing, marketing, labeling, packaging, and selling" the product. *Id.* at ¶ 64. Thus, the plaintiffs' concern that Bard is misconstruing the plaintiffs' negligence claim is meritless; Bard simply chose to address the plaintiffs' different theories of negligence separately. However, apart from reciting allegations that form the plaintiffs' failure to warn and design defect claims, the plaintiffs do not offer sufficient support to create a genuine dispute that Bard breached a legal duty that caused the plaintiffs' injuries in its inspection, marketing, labeling, packaging, or selling of the product. Accordingly, Bard's Motion on these points is **GRANTED.**

After considering the parties' proffered arguments and evidence, I **FIND** that

genuine disputes of material fact exist regarding the plaintiffs' remaining claims. Accordingly, to the extent Bard's Motion challenges any other claims, the Motion is **DENIED**.

b. Bard's Motion for Partial Summary Judgment [ECF No. 43]

The question of whether a plaintiff is entitled to punitive damages often involves an interlocking web of factual determinations respecting the defendant's conduct. The evidentiary record is frequently muddled enough on the point that genuine issues of material fact remain. That is the case here. Consequently, Bard is not, at least at this stage of the case, entitled to judgment as a matter of law on the punitive damages claim. Thus, the Motion for Partial Summary Judgment [ECF No. 43] is **DENIED**.

c. Specific Causation Daubert Motions [ECF Nos. 47, 49, 51, 53, 55, 57, 59, 62, 64, 66, 68, 70, 72, 74, 76, 78, 79, 81, 82, 83, 88, 89, 91, 92, 93, 95, 96, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 183]

Many of the *Daubert* motions filed in this MDL raise the same or similar objections. One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because

the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See id.* at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information the defendant did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about the defendant's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as any *Daubert* motion in this case challenges the FDA-related testimony discussed here, the motions are **GRANTED**.

The parties have identified more experts than can ever be called in a trial of any reasonable length. In this case alone, the parties have filed forty separate *Daubert* motions. Thus, I have considered principles of good judicial efficiency and proper management of judicial resources, and I now determine that substantive rulings on these motions are better suited for cases that will actually be tried on the merits. Accordingly, all remaining *Daubert* challenges to expert testimony in this case are **RESERVED** for trial.

d. The plaintiffs' Motion to Withdraw and Refile [ECF No. 157]

For reasons appearing to the court, the plaintiff's Motion to Withdraw and Refile [ECF No. 157] is **DENIED as moot**.

IV. Conclusion

The court **ORDERS** that:

- Bard's Motion for Summary Judgment [ECF No. 45] is **GRANTED in part** and **DENIED in part**;
- Bard's Motion for Partial Summary Judgment [ECF No. 43] is **DENIED**;
- The specific causation Motions [ECF Nos. 47, 49, 51, 53, 55, 57, 59, 62, 64, 66, 68, 70, 72, 74, 76, 78, 79, 81, 82, 83, 88, 89, 91, 92, 93, 95, 96, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 183], to the extent that the parties seek relief that is consistent with this Memorandum Opinion & Order, are **GRANTED in part**. In all other respects, the court **ORDERS** that the parties' motions are **RESERVED in part**; and
- The plaintiffs' Motion to Withdraw and Refile [ECF No. 157] is **DENIED as moot**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 22, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE